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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/489,884 | 01/21/2000 | Terry R. Colbert | P04348US0-PHI-1194 | 6401 |

27310 7590 09/11/2002

PIONEER HI-BRED INTERNATIONAL INC.
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EXAMINER

KRUSE, DAVID II

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 09/11/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,884

Applicant(s)

COLBERT, TERRY R.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4 and 20 is/are allowed.
- 6) ☒ Claim(s) 5-19 and 21-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 2 July 2002 has been entered.

Status of the Application

2. The objection to claims 1 and 5 is withdrawn in view of Applicant's amendments to said claims to include the ATCC Accession Number.
3. The rejection of claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Cunnyngnam (US Patent 6,087,564, filed 13 February 1998) is withdrawn in view of Applicant's arguments on page 4 of the Remarks.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

5. Claims 6, 12, 16 are objected to because of the following informalities: At claim 6, the phrase "A tissue culture" should read -- The tissue culture -- in referring to claim 5. At claims 12 and 16, the phrase "A hybrid maize plant" should read -- The hybrid maize plant -- in referring to claim 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 5-11, 13-19, 22-24 and 26-32 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 5, line 3, the phrase "the tissue regenerates" lacks a proper antecedent basis within the claim, the phrase -- the cells regenerate -- is suggested.

At claims 5 and 7, the phrase "capable of expressing...characteristics" is indefinite because characteristics are not "expressed", proteins are expressed and the characteristics are the consequence of protein expression. The phrase "having...characteristics" is suggested because the plant either has the characteristics or it doesn't.

At claim 6, the phrase "the cells or protoplasts being from a tissue" is indefinite because it is unclear what the metes and bounds of "being from" are. In addition, the term "protoplasts" lacks a proper antecedent basis in the claim. It is suggested that the phrase read -- the cells or protoplasts of said cells having been isolated from a tissue --.

Claim 7 is indefinite because at line 1, the maize plant or its parts cannot be regenerated from the tissue culture of claim 5, said maize plant must be regenerated from the cells of the tissue culture of claim 5. Appropriate correction is required.

Claims 8 and 21 are indefinite because the plant of claim 2 is not male sterile and thus it is unclear what the metes and bounds of the claim are.

Claims 9, 13, 17, 22, 26 and 30 are indefinite because said claims are directed to a method for developing a maize plant, yet said claims only recite the step of obtaining

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a maize plant or its part as a source of breeding material. There are no other positive method steps leading to the development of a maize plant in the claims. See MPEP § 2172.01.

At claims 11, 15, 19, 24, 28 and 32, the terms "yield ability", "food grade quality", "test weight" and "suited to the Southcentral region of the United States", for example, are relative and do not state the metes and bounds of the claimed invention. Even given the comparative statistical limitation in the instant claims, said terms do not denote properties specific to hybrid maize line '33T17' and thus do not state the metes and bounds of the claimed invention.

Claims 16 and 29 are indefinite because it is unclear how one skilled in the art could produce the maize plant of claim 2 or 20 containing one or more genes transferred by backcrossing. The claimed hybrid maize plant is evidently not the hybrid maize plant of claim 2 or 20, but a new and different product. In addition, the instant claim is directed to a product-by-process but there are not process steps recited by which one of skill in the art would or could produce the claimed product.

7. Claims 9-19 and 22-32 rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under current written description guidelines. The claims are drawn to corn progeny plants and transgenic corn plants having undisclosed identifying characteristics whereby only the characteristics of the

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deposited corn line '33T17' are known. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation. In addition, at claims 12-15 and 25-28 the effect of transgenes on the physiological and morphological characteristic of a transgenic '33T17' corn plant or progeny thereof, is not sufficiently described where by one of skill in the art could recognize the claimed corn plant. The breeding techniques encompass recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection and transformation and combinations thereof. Each of these breeding techniques would result in a structurally and phenotypically different plant. Over an undetermined number of generations, the identifying characteristics of each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification. To the extent that claims 16 and 29 reads on a corn plant wherein "one or more genes" are introduced by a backcrossing technique, it is unclear that Applicant could adequately describe such a plant because it is unclear that one of skill in the art could reproduce a '33T17' inbred corn plant that would have a single gene introduced by backcrossing from another, unidentified plant as broadly claimed (see below). While claims 11, 15, 19, 24, 28 and 32 set forth at least two '33T17' traits, because the terms used to describe the traits are relative terms, lacking a definitive comparative basis (see 112, second paragraph rejection above), these traits do not adequately define or distinguish '33T17' progeny plants. Furthermore, neither the

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individual traits themselves, nor their degree of expression, appear to be unique to the deposited corn line '33T17'. Accordingly, there is a lack of adequate description of the claimed progeny plants, in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. At claims 9, 10, 22 and 23, directed to a method for developing a maize plant, Applicant does not describe how to make and use the invention because Applicant has failed to adequately describe the intermediate products of the claimed methods by which one of skill in the art would arrive at an end product of the method, hence the claimed methods are not adequately described. Hence, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday 5, 2001/ Notices; p. 1099-1111).

Claim Rejections - 35 USC § 102

8. Claims 11-19 and 24-32 remain rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Cunnyingham (US Patent 6,087,564, filed 13 February 1998). This rejection is repeated for the reason of record as set forth in the last Office action mailed 5 April 2002. Applicant's arguments filed 2 July 2002 have been fully considered but they are not persuasive.

Applicant argues that a plant with the combination of two traits recited in the instant claims is not rendered anticipated or obvious from Cunnyingham. In addition, Applicant argues that it would require undue experimentation to begin with the hybrid of Cunnyingham which has its own unique combination of traits to breed with it to recover a hybrid with at least two of the traits enumerated in the instant claims (page 5, 3rd paragraph of the Remarks). The Examiner responds that undue experimentation is

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irrelevant to the instant rejection. The issue remains that the instant claims read on any plant comprising two '33T17' traits, traits that are not specifically unique to only the corn plant designated as '33T17', but which in fact occur in other corn plants, such as that taught by Cunnyingham. Given that Cunnyingham teaches at least two of the traits of '33T17', one of skill in the art would have had a reasonable expectation of success in transferring these traits.

Applicant argues that it must be recognized that the '33T17'-derived plants are themselves unusual and a nonobvious result of a combination of previously unknown and nonobvious genetics and that the phenotypic traits described, in each '33T17'-derived plant, has an additional benefit unique to each specific cross using '33T17' as one of its ancestors (page 5, 4th paragraph of the Remarks). The Examiner responds that one of skill in the art at the time of Applicant's invention would not be able to distinguish a maize plant having at least one ancestor being '33T17' and having at least two of the claimed traits from that taught by Cunnyingham for the reasons given in the last Office Action. Because there is no limitation in the instant claims directed to how many generations removed the claimed maize plant is from '33T17' taught by Applicant, the claimed maize plant could only comprise that genetic material from '33T17' that contributes to two of the claimed traits, but the remaining genetic material could be totally unrelated to '33T17', at which point one of skill in the art would not be able to recognize the source of the claimed traits. Alternatively, the claimed maize plant could retain no '33T17' genetic material, wherein the two claimed traits, expressed to the same degree as their expression in '33T17', could be the result of non-'33T17' genetic material.

The lack of adequate written description concerning transformed plants, plants comprising a gene introduced by backcrossing and method of using same are discussed *supra*. Given the limited guidance by Applicant about what characteristics a plant would have that has been transformed or has a gene introduced by backcrossing, claims 12-14, 16-18, 25-27 and 29-31 would have been *prima facie* obvious in view of Cunnyingham.

Conclusion

9. Claims 1-4 and 20 are allowed.
10. Claims 5-19 and 21-32 are rejected.
11. Claims 1-10, 12-14, 16-18, 20-23, 25-27 and 29-31 appear to be free of the prior art which neither teaches nor suggests hybrid maize plant '33T17' or method of using said hybrid maize plant.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

David H. Kruse, Ph.D.
6 September 2002

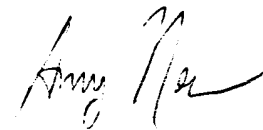
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Conclusion

9. Claims 1-4 and 20 are allowed.
10. Claims 5-19 and 21-32 are rejected.
11. Claims 1-10, *and*, 20-23, appear to be free of the prior art which neither teaches nor suggests hybrid maize plant '33T17' or method of using said hybrid maize plant.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.



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6 September 2002